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Docket Number (Optional)

PATENT APPLICATION TRA	ANSMITTAL L	ETTER		
To the Commissioner of Patents and Tradent Transmitted herewith for filing under 35 U.S. E. Alan Bates, Jeffrey Kovalik, Gentitled An assaying device consisting cap or cover which attaches onto the well or opening into which the Enclosed are:    X	C. 111 and 37 C ary Hoffman of the testhe cartridgue sample has tion, claims and at ,Inc.	t cartridge of cassette been deposit ostract.	or cassette e to cover ced	e with a
	NUMBER FILED	NUMBER EXTRA	RATE	FEE
BASIC FEE			\$730	\$730
TOTAL CLAIMS	<sup>23</sup> - 20 =	* 3	x \$22	66
INDEPENDENT CLAIMS	- 3 =	*	x \$76	
MULTIPLE DEPENDENT CLAIM PRESENT			\$240	
* NUMBER EXTRA MUST BE ZERO OR LARGER			TOTAL	\$ 796
If applicant has small entity 1.27, then divide total fee b			LL ENTITY TOTAL	<b>\$</b> 398
x A check in the amount of \$ 398	to cover th	ne filing fee is end	closed.	
The Commissioner is hereby authorized No as described be Charge the amount of \$	low. I have enclo	sed a duplicate of		eet.
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Charge the issue fee set in Allowance, pursuant to 37 (		the mailing of the	: Notice of	
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Date		Signature	)	
	Gary	/ Hoffman  Typed or print	ed name	
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	Pitt	sburgh PAddis	209-1935	



# **DTx**<sup>TM</sup>, Inc. P.O. Box 101299 Pittsburgh PA 15237

September 23, 1997

Commissioner of Patents and Trademarks Washington D.C. 20231

Dear Sir:

Enclosed are the following items:

- 1. Patent Application Transmittal Letter
- 2. Seven pages of written description, claims and abstract
- 3. Four sheets of drawings
- 4. Assignment of invention to DTx, Inc.
- 5. Declaration for Patent Application
- 6. Verified Statement claiming small entity status
- 7. Check in the amount of \$398 filing fee
- 8. Check in the amount of \$40 for recording of the Assignment

This patent application is related to Disclosure Document No. 420500 a copy of which is enclosed.

Sincerely,

Gary Hoffman

AN ASSAYING DEVICE CONSISTING OF THE TEST CARTRIDGE OR
CASSETTE WITH A CAP OR COVER WHICH ATTACHES ONTO THE
CARTRIDGE OR CASSETTE TO COVER AND SEAL THE WELL OR OPENING
INTO WHICH THE SAMPLE HAS BEEN DEPOSITED

# BACKGROUND

This invention generally relates to assaying devices and in particular the on-site immunoassay technology used to detect the presence of drugs in urine. On-site drug tests generally use an immunoassay method called antigen-antibody competitive binding to screen for the presence of drugs. Among the test kits used for such testing there are tests composed of a housing or container which contains a reagent test strip, an opening in which test results are displayed and a place for deposit of the sample. The sample wicks up into the reagent test strip and the results are displayed. The results are generally available within a few minutes. Often it is desirable to make a photocopy of the results, whether positive or negative, for a permanent record, since test results will change or disappear over time.

Possible problems include spilling of the sample, contamination of the sample, and contact by the test administrator or others with the sample during handling. A method is needed for a cleaner, more sanitary and easier handling of the test housing during and after the test administration, especially since specimens can be infectious. In order to photocopy the results, the test device is placed face down on the copier, so it is desirable to insure that sample will not leak onto the copier. Also a method is needed to insure a second sample from another donor is not inadvertently placed in the same test cartridge/cassette.

# SUMMARY OF THE INVENTION

The housing or cartridge/cassette of the present invention will have one or two openings or "windows" in which the test results are displayed and one or two wells or openings in the top of the cartridge/cassette for deposit of the sample. The sample is placed in the

well/opening by use of a pipette. The results will be displayed in the window. The cartridge/cassette and the cap or cover of the present invention will prevent the sample used in the test from spilling out, will prevent contamination of the sample, and will permit cleaner, more sanitary and easier handling of the cartridge/cassette during and after the wicking test process. The cap/cover when placed on the cartridge/cassette will provide a fluid tight relationship. The cartridge/cassette with the cap/cover provide a compact, easy to handle unit. The cap/cover if placed on the cartridge/cassette as soon as the sample begins wicking will prevent inadvertent commingling or intermixing of another sample.

It is the principal object of this invention to provide a convenient, compact, easily managed device for the containment of the sample.

It is also a further objective to provide a means to protect the sample from contamination once placed into the test well/opening.

It is a further objective to provide a means to protect the test administrator from undesirable contact with the sample while handling the test cartridge during the test administration.

It is a further objective to provide a means to protect the test administrator or others from undesirable contact with the sample during subsequent handling of the test cartridge.

It is a further objective of the present invention to provide a means of insuring that while photocopying the test results displayed in the test cartridge/cassette the sample will not leak from the well/opening onto the copier.

It is a further objective of the present invention to provide a means to prevent the test administrator from inadvertently commingling or intermixing a second sample from another donor.

These and other objects of the present invention will become readily apparent upon further review of the following specifications and drawings.

# BRIEF DESCRIPTION OF THE DRAWING

In the Drawing:

Figure 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top;

Figure 2 is a perspective view of the cartridge/cassette and cap/cover snapped or slipped together as seen from the front;

Figure 3 is a perspective view of the cartridge/cassette with two windows and two sample well/openings and the cap/cover separately as seen from the front or top.

Figure 4 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of edges on the cartridge/cassette and indentations on the cap/cover for further securing the cap/cover.

Figure 5 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of indentations on the cartridge/cassette and raised buttons on the cap/cover for further securing the cap/cover.

# DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top. The cartridge/cassette 1 contains an opening or window 2 in which the results on the test strip 3 will be displayed. The sample will be dropped into the well/opening 4 by means of a pipette. The cap/cover 5 has not been placed onto the cartridge/cassette yet.

Fig. 2 is a perspective view showing the cartridge/cassette and cap/cover snapped or slipped together. Fig. 2 is a view as seen from the front or top. The cartridge/cassette 1 with the results window 2 has the cap/cover 5 snapped or slipped into place. The sample well/opening, 4 in the other Figures, is now covered and sealed by the cap/cover 5 in a fluid tight relationship.

Fig. 3 shows a cartridge/cassette 1 with two results windows 2, two test strips 3, two sample well/openings with a connecting channel 4 and a separate cap/cover 5. This type of cartridge/cassette will accommodate more separate tests and requires a greater quantity of the sample.

Fig. 4 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with a raised edge 6 and the cap/cover (shown in cross section) with indentations 7 which when snapped together will further insure the attachment.

Fig. 5 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with an indentation 6 and the cap/cover (shown in cross section) with a raised button 7 which when snapped together will further insure the attachment. The end of the cartridge/cassette where the well/opening is located has been reduced in thickness with the result that when the cap/cover is attached it will be flush with the edges of the cassette/cover.

What is claimed is new and to be protected as set forth in the appended claims. Obviously although the embodiments described herein are the preferred one, modifications can be made to the shape of the cartridge/cassette and the cap/cover, without departing from the spirit and scope of this invention. The cartridge/cassette and the cap/cover may be formed or molded from any suitable material, usually plastic or other similar material, but the invention should work as well with most drug test materials. The cap is effective if it slips onto the cartridge/cassette snugly enough to insure that it will cover and seal the top of the sample well in a fluid tight relationship and will not detach. Raised buttons or edges can also be incorporated into the design of the cartridge/cassette and cap/cover to further insure that the cap/cover when snapped or slipped into place will not detach from the cartridge/cassette. The number of windows and urine well/openings shown are currently available, but more will not depart from the spirit and scope of this invention.

# **CLAIMS**

### What is claimed are:

- 1. An assaying device for depositing and analyzing a sample, comprising of: a cartridge/cassette means which contains the test strip, a window for viewing the test results and a well/opening for deposit of the sample; and a cap/cover means for sealing the top of the sample well in a fluid tight relationship.
- 2. An assaying device according to claim 1, which when attached together, further comprising means for containment of the sample used in the test.
- 3. An assaying device according to claim 1, which when attached together, further comprising means for protection of the sample from contamination during the test.
- 4. An assaying device according to claim 1, which when attached together, further comprising means for protection of the test administrator against contact with the sample during the test administration.
- 5. An assaying device according to claim 1, which when attached together, further comprising means for protection of the test administrator and others processing the test cartridge against contact with the sample during subsequent handling of the cartridge.
- 6. An assaying device according to claim 1, which when attached together, further comprising means for containment of the sample during photocopying of the test results.
- 7. An assaying device according to claim 1, which when attached together, further comprising means for insuring that a second sample from another donor is not placed into the well/opening.
- 8. A drug screening device for depositing and analyzing a urine sample, comprising of: a cartridge/cassette means which contains the drug test strip, a window for viewing the results and a well/opening for deposit of the urine sample, and a cap/cover means for sealing the top of the sample well in a fluid tight relationship.

- 9. A drug screening device according to claim 8, which when attached together, further comprising means for containment of the urine sample used in the drug test.
- 10. A drug screening device according to claim 8, which when attached together, further comprising means for protection of the urine sample from contamination during the drug test.
- 11. A drug screening device according to claim 8, which when attached together, further comprising means for protection of the test administrator against contact with the urine sample during the drug test administration.
- 12. A drug screening device according to claim 8, which when attached together, further comprising means for protection of the test administrator and others processing the drug test cartridge against contact with the urine sample during subsequent handling of the cartridge.
- 13. A drug screening device according to claim 8, which when attached together, further comprising means for containment of the urine sample during photocopying of the drug test results.
- 14. A drug screening device according to claim 8, which when attached together, further comprising means for insuring that a second urine sample from another donor is not placed into the well/opening.
- 15. A cap/cover article which when attached onto a test cartridge/cassette containing a reagent test strip, window for viewing the test results and a well/opening in the top of the cartridge/cassette for deposit of the test sample, covers and seals the top of sample well in a fluid tight relationship.
- 16. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for containment of the sample used in the test.
- 17. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for protection of the sample from contamination during the test.

- 18. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for protection of the test administrator against contact with the sample during the test administration.
- 19. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for protection of the test administrator and others processing the test cartridge against contact with the sample during subsequent handling of the cartridge/cassette.
- 20. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for containment of the sample during photocopying of the test results.
- 21. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for insuring that a second sample from another donor is not placed into the well/opening.
- 22. An assaying device according to claim 1, whereby the top of the sample well is secured in a fluid tight relationship.
- 23. A method of securing the top of the sample well of an assaying test device in a fluid tight relationship, comprising the steps of: depositing the test sample into the sample well of the cartridge/cassette; attaching the cap/cover to cover and seal the top of the sample well.

### ABSTRACT OF THE DISCLOSURE

An assaying device composed of a test cartridge/cassette and cap/cover which when attached together provide protection from contact with and contamination of the tested sample, provide for easier, cleaner handling of the test cartridge/cassette and prevent intermixing of another sample.

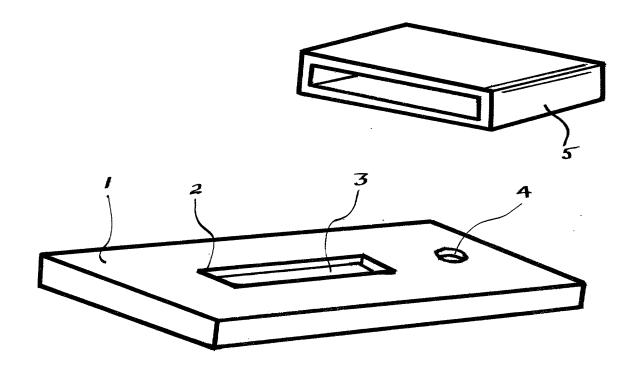


FIG. I

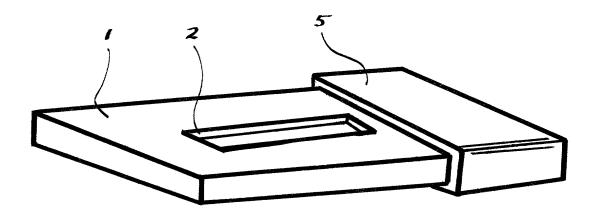
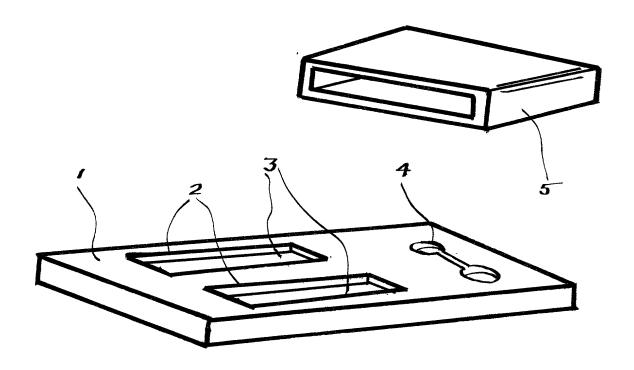
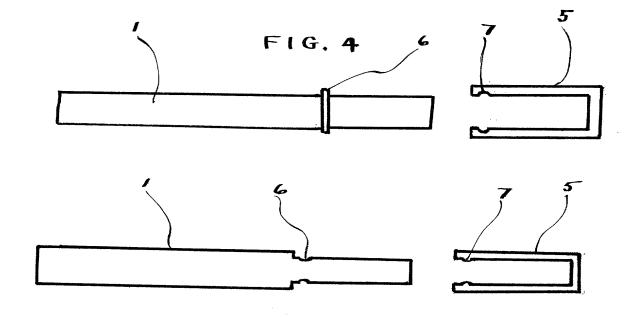


FIG.2



F16.3



F16.5

As a below named inventor, I hereby declare that:  My residence, post office address and citizenship are as stated below next to my name.  I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if any one name is listed below) or an original, first and joint inventor (if any one name is listed below) or an original, first and joint inventor (if any one name is listed below) or an original, first and joint inventor (if any one name is listed below) or an original, first and joint inventor (if any one name is listed below) or an original, first and joint inventor (and assaying device consisting of the test cartridge or cassette to cover and seal the statehed hereto unless the following box is checked: or opening into which the sample has been done as United States Application Number or PCT International Application Number and was filed on as United States Application Number or PCT International Application Number or PCT International Application on Number and was amended on (if application including the claims amended by any amendment referred to above.  I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.  I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application (s) for patent or inventor's certificate having a filling date before that of the application on which priority is claimed.  Prior Foreign Application(s)  (Number)  (Country)  (Day/Month/Year Filed)  (Number)  (Day/Month/Year Filed)  (Number)  (Country)  (Day/Month/Year Filed)  (The application in t	st office address and citizenship are as stated below next to my name.  original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural pelow) of the subject matter which is claimed and for which a patent is sought on the invention entitled device consisting of the test cartridge or cassette witthe specification of which re which attaches onto the cartridge or cassette to cover and seal the we call the specification of the popular or cassette to cover and seal the we call the specification in the property of the sample has been deposing as United States Application Number or PCT International Application and was amended on		hereby declare that:		1
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additional Sheet 1 of 1 Declaration for Patent Application

Full name of third joint inventor Third inventor's signature

Date Residence

Post Office Address Citizenship Gary Hoffman

9-22-97

285 Hawthorne Road Pittsburgh PA 15209-1935 same

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			OMB No. 0651-0011 (12/31/86)	
Applicant of Patentee:	E. Alan Bates,Jef	frey Kovalik, Gary	Hoffman Attorney's	
Serial or Patent No.: .			Docket No.:	
Filed or Issued:	device consisting	of the test cartri	dge or cassette with a cap or	
cover which att	caches onto the ca sample has been o	ertridge or cassette	e to cover and seal the well or	opening
v	ERIFIED STATEMENT STATUS (37 CFR 1.9 (f	(DECLARATION) CLAIM ) and 1.27 (b)) — INDEPEN	ING SMALL ENTITY NDENT INVENTOR	
poses of paying reduce Office with regard to	the invention entitled Al	n assaying device co	nventor as defined in 37 CFR 1.9 (c) for pur- d States Code, to the Patent and Trademark consisting of the test cartridge es onto the cartridge or cassett	
to co	ver and seal the v	well or opening into	o which the sample has been depo	sited
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or license, any rights in 1.9 (c) if that person had 37 CFR 1.9 (d) or a no	n the invention to any per- ad made the invention, or onprofit organization und	to any concern which would der 37 CFR 1.9 (e).	under contract or law to assign, grant, convey ed as an independent inventor under 37 CFR not qualify as a small business concern under veyed, or licensed or am under an obligation	
Each person, concern of under contract or law	or organization to which i to assign, grant, convey,	or license any rights in the i	nvention is listed below:	
[ ] no such perso	on, concern, or organizat	ion		
	cerns or organizations list		•	
*NOTE: S	eparate verified statement	s are required from each nan	ned person, concern or organiza-	
tion having	g rights to the invention a	aveiling to their status as sur	all entities. (37 CFR 1.27)	
ELIL NAME DTX	, Inc.		all entities. (37 CFR 1.27)	
FULL NAME DTX ADDRESS 285	, Inc. Hawthorne Road	Pittsburgh PA 1520	9-1935	-,
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FULL NAME	Hawthorne Road  INDIVIDUAL  INDIVIDUAL  INDIVIDUAL  INDIVIDUAL  INDIVIDUAL  I to file, in this application fatus prior to paying, or a which status as a small error to be true; and further that the repunishable by fine or infillful false statements mains verified statement is displayed by the prior of the punishable by fine or infillful false statement is displayed by the prior of the punishable by fine or infillful false statement is displayed by the prior of the punishable by fine or infillful false statement is displayed by the prior of the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the punishable by fine or infillful false statement is displayed by the	Pittsburgh PA 1520 X   SMALL BUSINESS CONCERN      SMALL BUSINESS CONCERN      SMALL BUSINESS CONCERN    or patent, notification of are at the time of paying, the earnity is no longer appropriate of my own knowledge are true these statements were made with marking the statements were made with the properties of the control of the cont	9-1935    I NONPROFIT ORGANIZATION    I NONPROFIT ORGANIZA	
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